Complete Summary

GUIDELINE TITLE

Diagnosis and treatment of cervical carcinomas.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Diagnosis and treatment of cervical carcinomas. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2002 May. 13 p. (ACOG practice bulletin; no. 35). [58 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American College of Obstetricians and Gynecologists (ACOG). Diagnosis and treatment of cervical carcinomas. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2000 Oct.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Cervical carcinomas

- Squamous cell carcinoma
- Adenocarcinoma

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Risk Assessment
Treatment

CLINICAL SPECIALTY

Obstetrics and Gynecology
Oncology
Radiation Oncology
Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To describe staging criteria and treatment for cervical carcinoma

TARGET POPULATION

Female patients, including pregnant women, with diagnosed or suspected cervical carcinoma

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Assessment

1. Staging of cervical cancer using the International Federation of Gynecology and Obstetrics (FIGO) system
    - Careful clinical examination including inspection, palpation, colposcopy, endocervical curettage, hysteroscopy, cystoscopy, proctoscopy, intravenous pyelography, and x-ray examination of lungs and skeleton
    - Colposcopic biopsy
    - Cone biopsy
    - Histology
    - Optional tests such as ultrasonography, computed tomography (CT), magnetic resonance imaging (MRI), lymphangiography, laparoscopy, fine needle aspiration

For evaluation of patients with abnormal cytology during pregnancy, refer to the algorithm in the original guideline document.

Management/Treatment

1. Microinvasive carcinoma

- Simple hysterectomy for stage Ia1
- Radical hysterectomy and pelvic lymphadenectomy for stage Ia2

2. Early-stage (Ib-IIa) carcinoma
    - Radical hysterectomy and pelvic lymphadenectomy
    - Primary radiation therapy with external beam radiation and either high-dose-rate or low-dose-rate brachytherapy
    - Combined adjuvant cisplatin-based chemotherapy and radiation therapy
3. Late-stage (IIb or later) carcinoma
    - Primary radiation therapy
    - Brachytherapy
    - Combined cisplatin-based chemotherapy and radiation therapy

Note: Addition of agents such as hydroxyurea or hypoxic cell sensitizers was considered but not recommended.

Follow-up

1. Thrice-yearly examinations for the first 2 years and twice-yearly visits subsequently to year 5
2. Papanicolaou (Pap) tests and chest x-rays on a yearly basis

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of radiologic tests
- Disease-free and overall survival rate

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' (ACOG's) own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985 and December 2000. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document.

Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force.

I Evidence obtained from at least one properly designed randomized controlled trial

II-1 Evidence obtained from well-designed controlled trials without randomization

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician-gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Grade C recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A - Recommendations are based on good and consistent scientific evidence.

Level B - Recommendations are based on limited or inconsistent scientific evidence.

Level C - Recommendations are based primarily on consensus and expert opinion.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of evidence (I-III) and levels of recommendations (A-C) are defined at the end of "Major Recommendations."

Guidelines for Clinical Staging of Invasive Cervical Carcinoma

- Examinations should include inspection, palpation, colposcopy, endocervical curettage, hysteroscopy, cystoscopy, proctoscopy, intravenous pyelography, and x-ray examination of lungs and skeleton.
- Conization of the cervix is considered a clinical examination.
- Suspected bladder or rectal involvement should be confirmed histologically.
- If there is a question about the most appropriate stage, the earlier stage should be assigned.

These guidelines are made up of examinations generally available throughout the world. Strict adherence to the rules for staging provides the framework for making valid scientific comparison of results.

It is recommended that the International Federation of Gynecology and Obstetrics (FIGO) system for staging of gynecologic cancer be used to facilitate comparisons

of international data. Refer to the original guideline document for FIGO nomenclature for cancer of the cervix.

The following recommendations are based on good and consistent scientific evidence (Level A):

- For stage Ib and selected IIa carcinomas of the cervix, either radical hysterectomy and lymph node dissection or radiation therapy with cisplatin-based chemotherapy should be considered. Adjuvant radiation therapy may be required in those treated surgically, based on pathologic risk factors, especially in those with stage Ib2 carcinoma.
- Stage IIb and greater should be treated with external-beam and brachytherapy radiation and concurrent cisplatin-based chemotherapy.

The following recommendations are based on limited or inconsistent scientific evidence (Level B):

- For stage Ia1 microinvasive squamous carcinoma of the cervix, treatment with conization of the cervix or simple extrafascial hysterectomy may be considered.
- Stage Ia2 invasive squamous carcinoma of the cervix should be treated with radical hysterectomy with lymph node dissection or radiation therapy, depending on clinical circumstances.
- Stage Ib1 should be distinguished from stage Ib2 carcinoma of the cervix because the distinction predicts nodal involvement and overall survival and may, therefore, affect treatment and outcome.
- Patients with squamous cell cancers and those with adenocarcinomas should be managed similarly, except for those with microinvasive disease. Criteria for microinvasive adenocarcinomas have not been established.

The following recommendations are based primarily on expert opinion and consensus (Level C):

- Following treatment for cervical carcinoma, patients should be monitored regularly, for example, with thrice-yearly follow-up examinations for the first 2 years and twice-yearly visits subsequently to year 5, with Papanicolaou (Pap) tests annually and chest x-rays annually for up to 5 years.
- Treatment for pregnant patients with invasive carcinoma of the cervix should be individualized on the basis of evaluation of maternal and fetal risks.

Definitions:

Grades of Evidence

I Evidence obtained from at least one properly designed randomized controlled trial

II-1 Evidence obtained from well-designed controlled trials without randomization

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

Levels of Recommendations

Level A - Recommendations are based on good and consistent scientific evidence.

Level B - Recommendations are based on limited or inconsistent scientific evidence.

Level C - Recommendations are based primarily on consensus and expert opinion.

CLINICAL ALGORITHM(S)

An algorithm is provided in the original guideline document for "Evaluation of the Patient with Abnormal Cytology During Pregnancy."

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate staging and treatment of cervical cancer

POTENTIAL HARMS

- Risks involved in treatment, including adverse effects of radiation and chemotherapy and surgical complications
- Treatment for pregnant patients with invasive cervical carcinoma should be individualized on the basis of evaluation of maternal and fetal risks.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the

needs of the individual patient, resources, and limitations unique to the institution or type of practice.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 (revised 2002 May)

GUIDELINE DEVELOPER(S)

American College of Obstetricians and Gynecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Obstetricians and Gynecologists (ACOG)

GUIDELINE COMMITTEE

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Gynecology

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

Electronic copies: Not available at this time.

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on February 4, 2004. The information was verified by the guideline developer on July 26, 2004.

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Date Modified: 9/25/2006